

REMARKS

As the claims are not currently amended, a claim listing is not included with the present Response. Since the Amendment of November 9, 2010 was entered, claim 1 is the sole pending claim.

In the Final Office Action, independent claim 1, as well as dependent claims 3, 5-7 and 9-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,254,348 to Hoffman et al., in view of U.S. Patent No. 5,185,212 to Spada et al. and WO 86/06281 to Wick. As discussed in the Amendment of November 9, 2010, this rejection was rendered moot, as the features of canceled claim 13 were incorporated into claim 1. Dependent claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over Hoffman, Spada and Wick, further in view of U.S. Patent No. 6,632,906 to Kamiyama. Thus, claim 1 is discussed below with respect to Hoffman, Spada, Wick, and Kamiyama.

Claim 1 recites a tulobuterol adhesive patch which comprises, *inter alia*, an acrylic-based pressure-sensitive adhesive agent which is a copolymer of 2-acetoacetoxyethyl (meth)acrylate, diacetoneacrylamide, tetraethyleneglycol dimethacrylate, 2-ethylhexylacrylate and methylmethacrylate. The amount of 2-acetoacetoxyethyl (meth)acrylate is 10-45 wt% of the acrylic pressure-sensitive adhesive copolymer.

On p. 9 of the Final Action, it was suggested that Applicants provide data concerning the 2-acetoacetoxyethyl (meth)acrylate (AAEM) of claim 1, and specifically how it compares to the styrene-1,3-diene-styrene (SDS) block copolymer of Hoffman. The Advisory Action recommended that Applicants compare Example 1 of the present application with an identical composition, where the polymer of Hoffman is substituted for the AAEM of claim 1.

In response, Applicants respectfully submit the declaration of inventor Naohisa

Kawamura, which is filed herewith. In the Amendment After Final of November 9, 2010, Applicants argued that the SDS block copolymer of Hoffman is a synthetic rubber adhesive, and would therefore perform as poorly as the patch of Comparative Example 3 (CE3) of the present specification (§41). The Kawamura declaration confirms this assertion.

The patch used in CE3 was called "H Tape," and was manufactured by a company named Nitto Denko. It is described in detail in International Application Publication No. 97/14411 (the "411 Publication"), and to the knowledge of inventor Kawamura, was the only commercially available tulobuterol patch available in Japan at the time the data shown in the present application was collected (Kawamura declaration, ¶8). The particular patch used in CE3 contained the synthetic rubber polyisobutylene (Kawamura declaration, ¶9). The '411 Publication lists several permissible synthetic rubbers that can be used in the patch disclosed therein, which include the polyisobutylene of CE3, as well as SDS, which is substantially the same polymer used in Hoffman (Kawamura declaration, ¶9).

The listing of the synthetic rubbers in a group in the '411 Publication would establish to one skilled in the art that they are substantially equivalent for purposes of use in a tulobuterol adhesive patch. Accordingly, the AAEM of claim 1 performs much more favorably than the SDS of Hoffman would, since the SDS of Hoffman is substantially equivalent to the polyisobutylene of CE3 (Kawamura declaration, ¶9). The SDS of Hoffman would thus exhibit extremely undesirable performance in several key areas important in tulobuterol patches (Kawamura declaration, ¶7).

In addition, as recited in claim 1, the amount of AAEM in the adhesive agent is from 10-45 wt%. As discussed in the Supplemental Response After Final of November 19, 2010 and acknowledged in the Final Action, the amount of AAEM in Spada, by contrast, varies from 1-2%. This is a significant difference, as the ratio of AAEM in the adhesive agent of the present claims is at least five times greater than what is shown in the cited references.

As stated in the Kawamura declaration, the amount of AAEM recited in claim 1 is critical. If the amount of AAEM were to drop below 10 wt%, critical properties such as the oily-substance holding power and cohesive strength would be adversely affected (Kawamura declaration, ¶11). Thus, even if the combination of Hoffman and Spada were proper, the combination would recite an amount of AAEM well outside of what is recited in claim 1. Since the amount of AAEM in claim 1 is critical, the combination of Hoffman and Spada fails to disclose or suggest the recited amount of AAEM.

Furthermore, as previously stated in the Amendment After Final of November 9, 2010, the SDS block copolymer is essential to the invention of Hoffman, and cannot be removed, as suggested in the Final Action. According to the MPEP and established case law, the proposed modification of a primary reference with a secondary one cannot render the prior art unsatisfactory for its intended purpose. MPEP §2143.01(V). Since SDS is essential to the invention of Hoffman, it cannot merely be removed and replaced with the AAEM of Spada, as set forth in the Final Action, since it would render the patch of Hoffman unsatisfactory.

In response to the Advisory Action's assertion that Applicants have not provided evidence of the above assertion, Hoffman states repeatedly that the entire invention is based on the combination of tulobuterol and SDS (Abstract, col. 2, l. 53-58, col. 3, l. 25-29). This is because the SDS polymer is particularly well adapted to improve the structural stability (col. 3, l. 25-26) and release rate (col. 8, l. 9-14) of tulobuterol. Comparative tests with salbutamol did not provide as favorable results, further establishing the critical combination of SDS and tulobuterol (col. 8, l. 9-14). Thus, one of ordinary skill in the art would understand that the SDS of Hoffman cannot be removed and swapped with the AAEM of Spada (Kawamura declaration, ¶10). To do so would render the patch of Hoffman unsuitable for its intended purpose, contrary to the requirements of the MPEP.

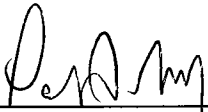
Accordingly, claim 1 is patentable over Hoffman, Spada, Wick, and Kamiyama.

Applicants respectfully request reconsideration and withdrawal of the rejection.

In view of the foregoing, Applicants respectfully submit the present application is in condition for allowance. Such action is solicited.

Respectfully submitted,

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